The Relationship Between Hospital Volume and Outcome in Bariatric Surgery at Academic Medical Centers

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Objective: To examine the effect of hospital volume of bariatric surgery on morbidity, mortality, and costs at academic centers.

Summary Background Data: The American Society for Bariatric Surgery recently proposed categorization of certain bariatric surgery centers as "Centers of Excellence." Some of the proposed inclusion criteria were hospital volume and operative outcomes. The volume–outcome relationship has been well established in several complex abdominal operations; however, few studies have examined this relationship in patients undergoing bariatric surgery.

Methods: Using the *International Classification of Diseases*, 9th edition, diagnosis and procedure codes, we obtained data from the University HealthSystem Consortium Clinical Data Base for all patients who underwent Roux-en-Y gastric bypass for the treatment of morbid obesity between 1999 and 2002 (n = 24,166). Outcomes of bariatric surgery, including length of hospital stay, 30-day readmission, morbidity, observed and expected (risk-adjusted) mortality, and costs were compared between high-volume (>100 cases/year), medium-volume (50–100 cases/year), and low-volume hospitals (<50 cases/year).

Results: There were 22 high-volume (n = 13,810), 27 medium-volume (n = 7634), and 44 low-volume (n = 2722) hospitals included in our study. Compared with low-volume hospitals, patients who underwent gastric bypass at high-volume hospitals had a shorter length of hospital stay (3.8 versus 5.1 days, $P < 0.01$), lower overall complications (10.2% versus 14.5%, $P < 0.01$), lower complications of medical care (7.8% versus 10.8%, $P < 0.01$), and lower costs ($10,292 versus $13,908, $P < 0.01$). The expected mortality rate was similar between high- and low-volume hospitals (0.6% versus 0.6%), demonstrating similarities in characteristics and severity of illness between groups. The observed mortality, however, was significantly lower at high-volume hospitals (0.3% versus 1.2%, $P < 0.01$). In a subset of patients older than 55 years, the observed mortality was 0.9% at high-volume centers compared with 3.1% at low-volume centers ($P < 0.01$).

Conclusions: Bariatric surgery performed at hospitals with more than 100 cases annually is associated with a shorter length of stay, lower morbidity and mortality, and decreased costs. This volume–outcome relationship is even more pronounced for a subset of patients older than 55 years, for whom in-hospital mortality was 3-fold higher at low-volume compared with high-volume hospitals. High-volume hospitals also have a lower rate of overall postoperative and medical care complications, which may be related in part to formalization of the structures and processes of care.

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In an effort to improve the quality of surgical care for bariatric patients, the American Society for Bariatric Surgery (ASBS) recently proposed categorization of certain bariatric surgical practices into "Centers of Excellence" for bariatric surgery. The Centers of Excellence program was initiated to educate the public and third-party payers about bariatric surgery centers that provide a comprehensive, standardized, and predictable structure along with a long-term commitment to the treatment of morbidly obese patients. Criteria for becoming a center of excellence include a threshold volume of bariatric surgical cases per year, operative outcomes, and the presence of a multidisciplinary commitment to management of the morbidly obese (Table 1). Bariatric centers that perform a threshold of 125 cases per year with acceptable results, provide long-term follow-up care, and have a mutidisciplinary approach for management of morbidly obese patients would be categorized as "centers of excellence." This concept was viewed with skepticism by some ASBS members as an effort to enhance regionalization of practice and reinforce referral to established centers. Furthermore, the validity of the hypothesis that high surgical volume in bariatric surgery equates to better operative outcomes and improved quality of care was questioned.

The relationship between volume and outcome has been established in several complex abdominal operations including esophagectomy and pancreatectomy, but few stud-

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The information contained in this article was based on the Clinical Data Base provided by the University HealthSystem Consortium.

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TABLE 1. Proposed Criteria for Becoming a Center of Excellence According to the American Society for Bariatric Surgery

- Institutional commitment to in-service education program
- Perform >125 bariatric surgical cases per year
- Bariatric Medical Director in decision loop
- Full consultative staff and critical care services
- Full line of equipment and instruments for the care of bariatric surgical patients
- Bariatric surgeon with 51% of practice in bariatrics
- Perioperative care standardized with utilization of clinical pathways
- Designated nurse or physician extenders for care and education of bariatric patients
- Availability of organized and supervised support groups
- Long-term follow-up with a system for outcome reporting

ies have examined the volume–outcome relationship in patients undergoing bariatric surgery.[1–5] Bariatric surgery, particularly Roux-en-Y gastric bypass, is a complex operation performed in a high-risk population with many comorbid conditions. Optimal outcomes in bariatric surgery often depend on the presence of an experienced surgical team working in the context of a well-structured multidisciplinary program. A dedicated surgical team often includes well-trained surgeons, bariatric surgical coordinators, dedicated anesthesiologists, nutritionists, and mental health specialists. A well-structured program includes a hospital facility capable of handling the morbidly obese and the presence of appropriate consultative and critical care staff, experienced nursing staff, perioperative clinical pathways, organized support group, and a clinic system in place for long-term follow-up of patients. The objective of this study was to determine the volume–outcome relationship in patients who underwent bariatric surgery by using a national administrative database of academic medical centers and teaching hospitals.

METHODS

Database

The University HealthSystem Consortium (UHC) Clinical Data Base is an administrative, clinical, and financial database that provides benchmark measures and an understanding of the use of health care resources for the purpose of comparative data analysis between academic institutions. The UHC database is a collection of patient-level all-payer hospital UB-92 and discharge abstract data from academic health centers and affiliate community hospitals. It contains discharge information on inpatient hospital stay such as patient characteristics, postoperative length of stay, 30-day readmission, overall and specific postoperative morbidity, including complications of medical care, observed and expected (risk-adjusted) in-hospital mortality, inpatient care costs, and discharge disposition. One of the benefits of the UHC Clinical Data Base is the risk-adjusted data for comparison of institutions. To ensure equitable interhospital comparisons, the UHC Data Base performs risk adjustment involving the following 4 steps: (1) assignment of a severity of illness estimate, (2) selection of a patient population to serve as the basis of the model, (3) use of multiple regression techniques to predict length of stay, cost, and probability of mortality based on the normative patient population, and (4) assignment of an expected length of stay, cost, and probability of mortality to every patient in the database. In addition, the refined diagnosis-related group methodology is used to assign a level of severity by grouping patients based on the severity and complexity of secondary diagnoses (comorbidities and complications). The severity class is grouped as baseline/low severity, moderate severity, major severity, or catastrophic severity. For example, comorbidities such as diabetes would be categorized as moderate severity and recent myocardial infarction as catastrophic severity. Approval for the use of the UHC patient-level data in this study was obtained from the institutional review board of the University of California, Irvine Medical Center and the UHC.

In-hospital mortality was defined as the percentage of patients who died before being discharged from the hospital. The UHC database has no information available on death occurring after discharge, even if the death occurred within 30 days of the date of surgery. Length of stay was defined as the period from index procedure to hospital discharge. Thirty-day readmission was defined as readmission for any reason within 30 days of discharge after the index procedure. Complications of medical care included medical errors, which can be defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve a particular aim. In the UHC database, 3 categories of complications (ie, iatrogenic complications, miscellaneous complications, and procedure-related perforations or lacerations) were used to analyze medical errors. Iatrogenic complications included iatrogenic hypotension and complications of medical care. Miscellaneous complications of procedures included ABO incompatibility reaction, Rh incompatibility reaction, and foreign body retained. Procedure-related perforations or lacerations included accidental puncture or laceration of organs such as the esophagus or intestine during a procedure. These 3 classifications of complications also included other complications unrelated to medical errors. The UHC clinical database provides an estimated cost of patient care using a ratio of cost to charge methodology. The UHC collects detailed patient charges at the revenue code level and estimates costs by multiplying charges by the *cost center-specific* ratio of cost to charges from the annual Medicare cost report submitted by hospitals.

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Data Analysis

We analyzed the UHC database for discharge data on all patients who underwent Roux-en-Y gastric bypass for the treatment of morbid obesity between January 1, 1999 and December 31, 2002. All hospitalizations during which a bariatric procedure (ie, Roux-en-Y gastric bypass) was performed for the treatment of morbid obesity were identified by appropriate diagnosis and procedural codes as specified by the *International Classification of Diseases*, 9th Edition, Clinical Modification (ICD-9-CM). The principal ICD-9 diagnosis codes for obesity and morbid obesity were used (278.0, 278.01, 278.00, and 278.1), including a subcategory of obesity and a subclassification of morbid obesity. The principal ICD-9 procedure codes for Roux-en-Y gastric bypass were used (44.31, 44.39, and 44.3), including a subcategory of gastroenterostomy without gastrectomy and a subclassification of high gastric bypass. Laparoscopic procedures cannot be differentiated from open procedures because no specific ICD-9 codes exist for laparoscopic gastric bypass. Therefore, to estimate the number of Roux-en-Y gastric bypass procedures performed laparoscopically, we identified all discharge abstracts that included a code for diagnostic laparoscopy, laparoscopic lysis of adhesions, or laparoscopic cholecystectomy (54.12, 54.51, and 51.23, respectively). To increase the homogeneity of the cohort, the diagnosis-related group for operative treatment of obesity (DRG 288) was also used, and patients undergoing emergent procedures were excluded.

We compared patient characteristics (age, sex, race, and severity class), perioperative outcomes, in-hospital mortality, and costs for patients who underwent bariatric surgery according to hospital surgical volume. Hospitals were divided into 3 groups based on the average number of bariatric operations performed within the 4-year period from 1999 to 2002. Hospital groups were determined by ranking all hospitals by volume. The annual hospital volume was categorized into high-volume (>100 cases/year), medium-volume (50–100 cases/year), or low-volume (<50 cases/year).

Statistical analysis was performed on observed and severity-adjusted data with SPSS statistical software, version 12.0 (SPSS Inc., Chicago, IL). Data are expressed as mean ± standard deviation. Differences in patient characteristics, complications, and 30-day readmission rates between high-, medium-, and low-volume hospitals were analyzed with gamma measures of ordinal association. Additional analyses were performed to determine differences between high- and low-volume hospitals with Pearson χ^2 tests. Bivariate analyses with one-way analysis of variance were performed to determine differences in length of stay and costs between the 3 groups. Parameters such as length of stay, 30-day readmission, observed and expected mortality, and costs were given as a mean variable for each institution. These values were weighted according to the number of cases performed at the respective institution. A P value of less than 0.05 was considered significant. Observed-to-expected mortality ratios were compared between high- and low-volume hospitals by calculating a 95% confidence interval. If the 2 confidence intervals overlapped, the difference between high- and low-volume hospitals was considered significant at the 0.05 level.

RESULTS

Patient Characteristics

From 1999 to 2002, a total of 24,166 patients underwent Roux-en-Y gastric bypass for the treatment of morbid obesity at 93 academic centers in the United States. As shown in Table 2, there were 22 high-volume (n = 13,810), 27 medium-volume (n = 7634), and 44 low-volume (n = 2722) hospitals. The mean number of cases performed per year was 157 at high-volume hospitals, 71 at medium-volume hospitals, and 15 at low-volume hospitals. The majority (83%) of patients were female. The 3 groups were similar with respect to age and gender. There was a higher proportion of Caucasians, a lower proportion of laparoscopic cases, and a higher proportion of patients with baseline/low severity at high-volume hospitals. For the entire group, the age distribution consisted of 0.3% of patients less than 18 years of age, 90.2% of patients between the ages of 18 and 54, and 9.5% of patients greater or equal to 55 years of age. The ethnicity distribution included 74.9% Caucasian, 12.6% African American, 3.3% Hispanic, 0.2% Asian, and 9.0% other. As shown in Fig. 1, the volume of Roux-en-Y gastric bypass increased from 2674 cases in 1999 to 9602 cases in 2002 (an increase of 259%). In addition, the number of institutions performing bariatric surgery increased from 64 in 1999 to 84 in 2002.

In-hospital Mortality

Between 1999 and 2002, the expected mortality (severity adjusted) was similar for high-, medium-, and low-volume hospitals at 0.6%; however, the observed in-hospital mortality was lower at high-volume hospitals (0.3%) than low-volume hospitals (1.2%, $P < 0.01$). The overall observed-to-expected in-hospital mortality ratio was higher at low-volume than high-volume hospitals (2.0 versus 0.6, respectively, $P < 0.05$). In a subset of patients greater than or equal to 55 years of age, the observed in-hospital mortality was 0.9% at high-volume hospitals and 3.1% at low-volume hospitals ($P < 0.01$). The observed-to-expected in-hospital mortality ratio was significantly higher at low-volume (3.9) than high-volume (1.2) hospitals (Fig. 2).

Perioperative Outcomes and Costs

The perioperative outcomes according to surgical volume are shown on Table 3. The mean length of hospital stay was 3.8 ± 2.9 days at high-volume hospitals compared with 5.1 ± 4.0 days at low-volume hospitals ($P < 0.01$). The

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TABLE 2. Patient Characteristics and Hospital Volume of Bariatric Surgery, 1999–2002

Variable	High-Volume N (%)	Medium-Volume N (%)	Low-Volume N (%)
No. of institutions	22	27	44
Total no. of cases	13,810	7634	2722
Mean no. of cases per institution per year	157	71	15
Age			
0–17 years	34 (0.2)	19 (0.2)	9 (0.3)
18–54 years	12,500 (90.5)	6821 (89.4)	2485 (91.3)
≥55 years	1276 (9.3)	794 (10.4)	228 (8.4)
Male gender	2347 (17.0)	1247 (16.3)	452 (16.6)
Race			
White	10,474 (75.8)*	5682 (74.4)	1957 (71.9)
African American	1706 (12.4)	1040 (13.6)	305 (11.2)
Hispanic	433 (3.1)	273 (3.6)	104 (3.8)
Asian	25 (0.2)	23 (0.3)	10 (0.4)
Other	1172 (8.5)*	616 (8.1)	346 (12.7)
Laparoscopic cases	951 (6.9%)*	1237 (16.2%)	260 (9.5%)
Severity class			
Baseline/low	9329 (67.5)*	4860 (63.7)	1644 (60.4)
Moderate	1998 (14.5)	1131 (14.8)	428 (15.7)
Major	1970 (14.3)*	1297 (17.0)	479 (17.6)
Catastrophic	513 (3.7)*	346 (4.5)	171 (6.3)

High-volume (>100 cases/year), medium-volume (50–100 cases/year), low-volume (<50 cases/year).
*$P < 0.05$ compared to low volume hospitals.

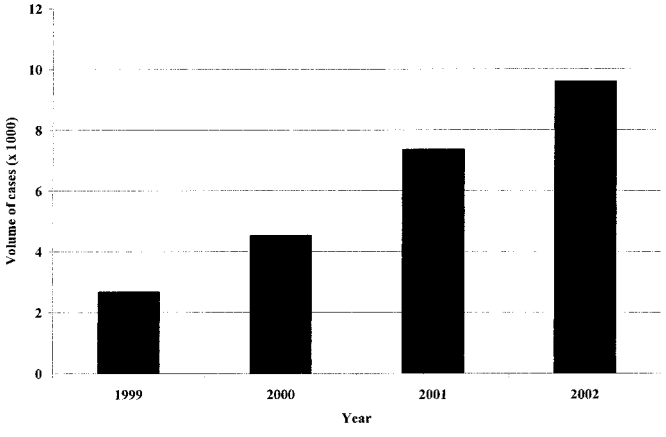

FIGURE 1. Volume of Roux-en-Y gastric bypass according to year, 1999–2002.

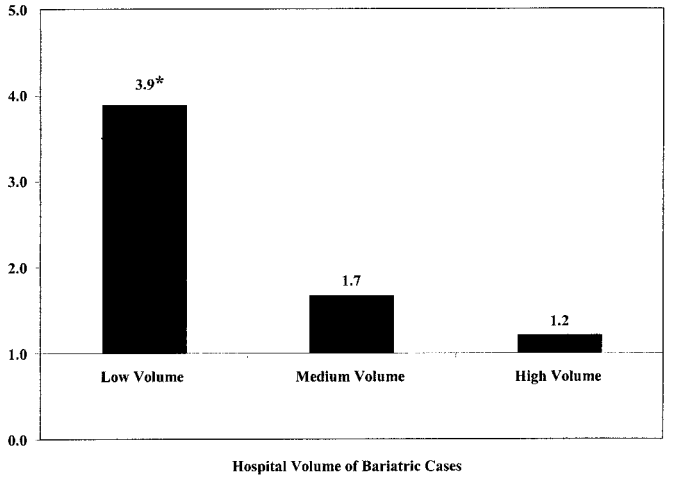

FIGURE 2. Observed-to-expected in-hospital mortality ratio for a subset of patients ≥ 55 years according to volume of bariatric surgery. *$P < 0.05$ compared with high-volume hospitals.

30-day overall readmission rate, not specific to procedure or diagnosis, was 0.6% at low-volume hospitals compared with 0.3% at high-volume hospitals ($P < 0.05$). The overall complication rate was significantly lower at high-volume hospitals than low-volume hospitals (10.2% versus 14.5%, respectively, $P < 0.01$). Compared with low-volume hospitals, high-volume hospitals had lower pulmonary complications (1.2% versus 3.1%, $P < 0.01$), complications of medical care (7.8% versus 10.8%, $P < 0.01$), and wound infections (1.0% versus 2.2%, $P < 0.01$). There were no significant differences in the rate of venous thrombosis/

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TABLE 3. Hospital Volume of Bariatric Surgery and Outcomes, 1999–2002

Outcomes	High-Volume	Medium-Volume	Low-Volume
Mean length of hospital stay (days)	3.8 ± 2.9*	4.4 ± 3.2	5.1 ± 4.0
Overall complications (%)	10.2*	12.3	14.5
Pulmonary complications (%)	1.2*	2.0	3.1
Complications of medical care (%)	7.8*	9.5	10.8
Wound infection (%)	1.0*	1.2	2.2
Pneumonia (%)	0.7	0.8	0.8
Venous thrombosis/pulmonary embolism (%)	0.3	0.3	0.4
Postprocedure hemorrhage (%)	1.3	1.4	1.5
30-day readmission (%)	0.3†	0.3	0.6
Mean cost ($)	10,292 ± 6680*	11,619 ± 7899	13,908 ± 9573
Disposition (%)			
Home	98.8*	98.1	95.8
Transferred‡	0.8*	1.3	2.8
Expired	0.3*	0.5	1.2
Unknown	0.1	0.1	0.2

High-volume (>100 cases/year), medium-volume (50–100 cases/year), low-volume (<50 cases/year).
*$P < 0.01$ compared to low-volume hospitals.
†$P < 0.05$ compared to low-volume hospitals.
‡ Transferred to skill nursing facility, intermediate care facility, or rehabilitation center.

pulmonary embolism, postprocedural hemorrhage, or pneumonia between groups. The percentage of patients who required transfer to a skilled nursing facility, intermediate care facility, or rehabilitation center after the index operation was higher for low-volume hospitals than high-volume hospitals (2.8% versus 0.8%, respectively, $P < 0.01$). The mean cost for a Roux-en-Y gastric bypass operation was significantly higher at low-volume hospitals compared with high-volume hospitals ($13,908 ± $9573 versus $10,292 ± $6680, respectively, $P < 0.01$).

DISCUSSION

With the recent surge in the number of bariatric operations being performed in the United States, the field of bariatric surgery has come under intense scrutiny by the public, media, and third-party payers concerning the safety and quality of care for bariatric patients.[6] The ASBS recognizes the importance of a comprehensive approach to surgical management for morbid obesity and recently proposed a Centers of Excellence accreditation program planned for implementation in the latter part of 2004. The ASBS used a threshold of 125 bariatric surgical cases per year as a measure of quality. Bariatric surgical cases include primary bariatric surgical operations or procedures performed for the care of bariatric surgical patients. Although the volume and outcome relationship in bariatric surgery has been examined and established at a statewide level, our study demonstrated a relationship between the volume of bariatric surgical cases and their outcome by using a large-scale national database.[5,7] Between 1999 and 2002, there were 24,166 patients who underwent Roux-en-Y gastric bypass for the treatment of morbid obesity at 93 academic centers. There were 22 high-volume hospitals, accounting for 24% of the academic centers in the database, but these hospitals performed 57% of the gastric bypass operations. Compared with low-volume hospitals, high-volume hospitals were associated with a lower mortality rate (a difference of 0.9%), shorter length of hospital stay, lower rate of 30-day readmission, and reduced overall complication rate. The rate of complications of medical care at high-volume hospitals was also lower than that of low-volume hospitals, which implies that the improved outcomes at high-volume hospitals could be related in part to more comprehensive structures and/or processes of care. The mean hospital cost for Roux-en-Y gastric bypass operation was $3616 lower at high-volume hospitals than at low-volume hospitals. Although we were able to find significance differences in the in-hospital mortality between high-volume hospitals and low-volume hospitals, clinical significance is limited because of a low overall mortality rate for gastric bypass surgery (approximately 0.5%). However, the volume–outcome relationship can still be established on the basis of other outcome measures including length of stay, 30-day readmission, and complications. In a subset of patients 55 years or older, the volume–outcome relationship was more pronounced in that the in-hospital mortality was 3-fold higher

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at low-volume hospitals than at high-volume hospitals (3.1% versus 0.9%, respectively).

One of the weaknesses in evaluating the volume–outcome relationship is the limited use of risk adjustment in most databases.[8] A frequent argument against the validity of the volume–outcome relationship is that low-volume hospitals tend to treat sicker patients who are socially disadvantaged and have more comorbidities. Therefore, risk adjustment is the key for establishing a valid comparison between high-volume and low-volume hospitals. The UHC database uses an extensive risk adjustment model and methodology to assign a probability of death termed "expected mortality" to each patient. The risk adjustment model takes into account several patient-specific variables, including the severity of illness. We found the expected mortality at high-volume hospitals to be similar to that of low-volume hospitals, demonstrating similarity in characteristics and severity of illness. The observed-to-expected mortality ratio for high-volume hospitals was 0.6, whereas the observed-to-expected mortality ratio for low-volume hospitals was 2.0. Although the observed in-hospital mortality at low-volume hospitals was only 1.2%, it should be noted that this number only represents in-hospital mortality for the index admission and can be falsely low because any deaths that occurred during readmission to the same or a different institution were not captured.

Although the hospital volume and outcome relationship has been established, the underlying causes that produce the association between volume and outcome are still largely unknown.[1,2,8] Most researchers do not believe that hospital volume in itself has a direct causal relationship with outcome. It is more likely that volume is a surrogate measure for structural and process components that are followed by necessity at high-volume hospitals and represent a higher quality of care.[7] The improved outcomes observed at hospitals performing a high-volume of bariatric surgery may be a reflection of the presence of appropriate structural characteristics and formalized processes of care. Important structural components at the physician level include experienced surgeons and health care professionals who implement standardized selection criteria, operative care, and postoperative care. Important structural components at the system level include appropriate hospital facilities, including large wheel chairs, beds, operating room tables, and other equipment necessary for the care of the morbidly obese, availability of diagnostic technology, critical care staffing, and other resources such as rehabilitation facilities appropriately equipped for the care of bariatric patients. Volume is one of the structural components. Surgeons at high-volume facilities have the ability to refine surgical techniques and thereby improve outcomes, representing the "the more you do, the better you are at it" hypothesis, and by extension are "less likely to make a mistake." The presence of an experienced surgical team that includes qualified physicians, nurses, and other health care professionals improves the patient selection process and perioperative clinical decision-making and likely results in a lower rate of medical errors, which has been shown to be associated with increased mortality.[9] The processes of care such as clinical pathways can improve resource use, lower complications, and also reduce in-hospital errors such as giving or omission of physician orders. Taken together, we believe that the above factors are the underlying reason for the observed improvement in outcome at high-volume hospitals.

Medical errors during hospitalization are a major health care issue and have been known to be associated with an increased risk of death, prolonged hospital stay, and increased resource use.[8] The 1999 Institute of Medicine report, *To Err is Human: Building a Safer Heath System*, emphasized that health care in the United States could be safer.[10] At least 44,000 people and as many as 98,000 people die in hospitals each year as a result of medical errors; this represents the eighth leading cause of death in the United States.[8] The types of errors include error or delay in diagnosis, failure to act on results of testing, error in performance of an operation, error in dose or method of using a drug, failure to provide prophylactic treatment, equipment failure, and other system failure. It is difficult to quantify the true rate of medical errors in any database, because the majority of these errors are complex and can be subjectively interpreted. Errors such as delay of diagnosis or inappropriate care may not be identified in any chart review. For example, an inexperienced surgical team can lead to a delay in diagnosis and inappropriate management of a postoperative anastomotic leak, which can result in significant morbidity and even mortality. However, there are certain types of medical errors that do not require subjective interpretation, such as technical errors during the procedure (the presence of a retained foreign body, iatrogenic perforation, iatrogenic splenectomy) or a system error of giving the wrong doses or types of medication or giving the wrong blood types/products. The results from our study demonstrated that the rate of complications of medical care was significantly lower at high-volume hospitals (7.8% versus 10.8%). This actual number may even be higher because errors in diagnosis or inappropriate care are not reflected in any database.

Regionalization of care implies referral of complex operations or patients with high-risk conditions to hospitals with characteristics shown to be associated with better outcomes.[8] Volume-based referral initiatives for several complex surgical procedures (esophagectomy, pancreatectomy, coronary artery bypass graft, percutaneous coronary intervention, and abdominal aortic aneurysm repair) have been advocated by health care organizations such as the Leapfrog group. Composed of more than 150 public and private organizations that provide health care benefits, the Leapfrog group represents over 34 million health care consumers in all 50 states. They use hospital volume as a proxy of quality and

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as the basis for evidence-based hospital referral. No such initiative has been established for bariatric surgery by the Leapfrog group. However, third-party payers such as Blue Cross of California have already created health care policies toward regionalization by establishing their own bariatric surgery center-of-excellence accreditation criteria. Therefore, it is important for surgical societies such as the ASBS to take a leading role in this credentialing process. The results from our study support the ASBS initiative in establishing the Centers of Excellence accreditation program. However, unlike complex procedures with high operative mortality such as esophagectomy and pancreatectomy, the available evidence may not be sufficient to warrant an overall effort at regionalization in bariatric surgery. Although statistically significant, the absolute difference in the observed in-hospital mortality was only 0.9% between high-volume and low-volume hospitals. In addition, some low-volume hospitals have outcomes comparable to that of high-volume hospitals. In this study, 27 (61%) of 44 low-volume institutions had a low (less than 1) observed-to-expected in-hospital mortality ratio. Our results, however, do support the selective referral of a higher-risk group of patients (age $\geq$ 55 years) to hospitals performing a high-volume of bariatric surgery. The observed-to-expected in-hospital mortality ratio was 3.9 at low-volume hospitals compared with 1.2 at high-volume hospitals. Advanced age has been shown to be an important factor associated with a higher risk of developing postoperative complications and mortality after gastric bypass; therefore, older patients would benefit most from referral to high-volume hospitals.[11,12]

There are many issues relating to the logistics of regionalization and its implications that need to be addressed. Even if better quality can be obtained at high-volume facilities, some patients are unwilling or unable to travel on multiple occasions to regional Centers of Excellence for care. Travel to high-volume hospitals also can be costly and not affordable by all patients. High-volume centers may not have the capability to handle the additional volume of cases. There are also potential financial implications such as inflation of costs at Centers of Excellence that monopolize care. Efforts to concentrate care at high-volume centers also may drive surgeons to lower their threshold to operate to increase the number of procedures performed. Lastly, patients who are able to travel long distances to have their operation performed at high-volume centers still face the difficulty of traveling long distances to receive continual long-term follow-up care.

This study has several limitations. The data used in this study was obtained from an administrative database that does not include patient weight or body mass index, which are important factors in computing risk adjustment of outcome. High body mass index ($>$50 kg/m^2) has been shown to be a predictive factor of complicated postoperative care.[13] The UHC database is compiled from discharge abstract data and is limited to in-hospital morbidity and mortality without outpatient follow-up data. For example, complications or deaths arising after discharge are not captured in this database. The coding of certain complications may be inaccurate because postoperative adverse events are subjectively defined by the surgeon and may be coded differently. However, in-hospital mortality, length of stay, 30-day readmission, and discharge status are accurate end points because they do not require subjective evaluation. The complications of medical care were analyzed with intent to examine the rate of medical errors. However, we found it necessary to combine 3 different categories of complications in the UHC database to encompass both surgically related errors (procedure-related perforations) and medical errors (eg, iatrogenic complications, miscellaneous complications). Our study was limited to academic centers, and the results may not be generalizable to nonacademic institutions. Lastly, the procedure codes did not allow us to accurately differentiate between laparoscopic and open procedures. One would assume that high-volume hospitals perform more laparoscopic procedures, which could account for some of the improved outcomes. However, our estimate of the proportion of laparoscopic cases was actually lower at high-volume hospitals.

Despite these limitations, this study provides a large sample size and is the first to provide evidence of a relationship between volume and outcome in bariatric surgery at the national level. In addition, the outcome data from this study may represent a set of acceptable standards of perioperative outcomes for Roux-en-Y gastric bypass, keeping in mind the aforementioned limitations.

CONCLUSIONS

This study analyzed the quality of bariatric surgery according to hospital volume using a national academic/teaching hospital administrative database. The major observation of our study was that in-hospital mortality was lower in hospitals that perform more than 100 bariatric surgical cases per year. Hospitals performing a high-volume of bariatric surgery also had a shorter length of hospital stay, lower 30-day readmission rate, lower perioperative morbidity, and decreased costs. The lower operative mortality at high-volume hospitals likely represents a complex interaction of organizational differences, physician and nurse expertise, processes of care, availability of consultant services, and access to technology and other resources that minimize adverse complications. In this study, the lower rate of complications of medical care at high-volume hospitals may represent an improved structural system or process of care that makes it less likely for health care professionals to err. Overall, the implication for regionalization of bariatric surgery may not have been answered adequately by this study. However, given the higher risk of mortality in a subset of high-risk patients 55 years or older, this group would achieve the most benefit from

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selective referral and regionalization. The results from this study support the ASBS initiative in creating guidelines for quality measurement and improvement. The goal of the accreditation program is to set a high standard that institutions providing care for bariatric patients should meet. The quality of care for bariatric surgical patients can be improved by referring high-risk surgical patients to high-volume hospitals and by improving the structure and formalizing the processes of care at lower-volume hospitals. Future outcomes studies in bariatric surgery should focus on effectively measuring the numerous organizational and clinical characteristics that are indicators of quality care and on developing a program for quality improvement with an emphasis on reducing medical errors.

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Discussions

DR. WALTER J. PORIES (GREENVILLE, SOUTH CAROLINA): Dr. Nguyen has offered us an important contribution. In bariatric surgery, the more you do, the better the outcomes. I would like, however, to take the focus away from volume. I don't think volume is the major factor. I think it is the system that counts, a system that prevents errors. To quote the authors, "bariatric surgery...is...complex, performed in a high-risk population with many co-morbid conditions." In bariatric surgery there are many chances for disastrous errors.

We can no longer afford to have every new bariatric center go through a learning curve as they accumulate the first 100 or 200 patients. Every lesson does not have to be re-learned.

I am grateful to Dr. Nguyen for mentioning the initiative of The American Society for Bariatric Surgery (ASBS) to recognize centers of excellence. The process is well under way.

To ensure credibility, the program will be managed by an arm's length, not-for-profit company named the Surgical Review Corporation, which is directed by a broadly based distinguished Board of Governors that includes our president, Dr. Scott Jones, as well as representatives from the industry, insurance carriers, Medicaid/Medicare, and a consumer. The first drafts of the requirements for provisional and full approval have been developed. The initial applications should be ready for distribution by July and we expect to recognize centers of excellence by the end of the year.

The objective is greater than just giving the Good Housekeeping Seal of Approval to hospitals and surgeons that do good work. We estimate that we will be accumulating data on at least 10,000 patients per year, verified by site visits. And let me emphasize that last phrase: verified by site visits. With that approach, we should be able to compare procedures, stratify risk, define indications, document costs, and really know what our outcomes are. More important, however, we should be able to determine what makes certain centers successful and, most important, how we can translate their approaches into new centers entering the field.

Again, Dr. Nguyen, we thank you. I do have 1 question—since every surgeon has to start with a small volume, how can we avoid that learning curve and, if so, how can we achieve that goal?

DR. NINH T. NGUYEN (ORANGE, CALIFORNIA): Thank you, Dr. Pories, for your comments. The term "learning curve" includes selection of the right patient; mastering the technique of the operation; understanding the nuances of postoperative care; and successful organization of a multidisciplinary team. Even with appropriate mentoring, the only way to avoid the "learning curve" is not to perform the operation. The learning curve for laparoscopic gastric bypass has been estimated between 75 to 100 cases. The primary goal is to minimize the extent of the learning curve. I think we can reduce the learning curve effectively with appropriate training provided by organizations such as the ASBS; close preceptorship and mentoring; development of multidisciplinary care paths for care for the morbidly obese; and implement and monitor guidelines for quality assessment.

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DR. BRUCE M. WOLFE (SACRAMENTO, CALIFORNIA): Thank you for your presentation of some important data may have far-reaching implications.

My questions are—what is the role of the individual surgeon performance in determination of the outcomes at specific centers? And how do you deal with that issue?

How many moderate or low-volume centers that in fact have satisfactory or better outcomes would be eliminated or disqualified if you in fact did limit bariatric surgery to the high volume centers only? This is an average database for all the centers in the database.

A related question—do you and your colleagues advocate such regionalization or concentration of cases at high volume centers only at this time or do we need more study of this problem before action is ready to be taken?

DR. NINH T. NGUYEN (ORANGE, CALIFORNIA): Thank you, Dr. Wolfe. The role of the individual surgeon was not examined in this study; however, a high-volume surgeon usually implies a high-volume hospital particularly for bariatric surgery. Indeed, even a high-volume surgeon would not normally perform bariatric surgery at several different institutions unless the underlying structure and process of care were in place for management of these patients. You questioned what happens in the case of a low-volume surgeon operating at a high-volume hospital. Will there be a good outcome? We did not examine specifically the role of the individual surgeon volume in this study but a recent report from Pittsburgh demonstrated that high-volume surgeons had significantly lower complications compared to low-volume surgeons.

Regionalization of care implies referral of patients to be treated at hospitals with characteristics associated with better outcomes. The results from our study do not support an overall effort at regionalization. However, there is a higher-risk subset of patients >55 years in whom the in-hospital mortality was 3.1%. This high-risk group of patients would benefit most from regionalization. The logistics of regionalization still must be overcome. Some patients are unwilling or unable to travel to centers for the frequent follow-up visits. Undoubtedly, there are financial implications when any center monopolizes a specific activity.

DR. BRUCE D. SCHIRMER (CHARLOTTESVILLE, VIRGINIA): I would like to congratulate Dr. Nguyen and his colleagues. I just wanted to echo a little bit of what Dr. Wolfe said. I am worried that this paper may send the wrong message to the surgeon who performs a modest number of cases.

For many years at our institution I did about 50 to 75 cases per year with pretty good results. My question for you, Dr. Nguyen, do you have any information as to whether some of these low-volume institutions were at the beginning of their experience? If there was an institution that was just starting, obviously we know from the learning curve that they would probably have poorer outcomes and results.

Secondly, I would also like to ask whether or not you would discourage the surgeon who plans to do about 50 cases per year from continuing to do that.

DR. NINH T. NGUYEN (ORANGE, CALIFORNIA): Dr. Schirmer, we would not discourage low-volume centers planning to perform about 50 cases per year. Remember that the correlation between volume and outcome is only true on average and not all low volume hospitals had poor outcomes. Specifically, 27 of 44 (61%) low-volume hospitals in this study had in-hospital mortality equivalent to or less than the expected mortality. Therefore, it is important for surgeons at low-volume hospitals to select appropriate candidates for bariatric surgery and monitor their outcomes with an understanding that high-risk patients (>55 years) may benefit from referral to regional high volume hospitals. We do not know if some of the low-volume institutions were at the beginning of their experience and that is one of the limitations in the use of administrative data.

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